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Authors	Benson, Philip E.;Alexander-Abt, Jonathan;Cotter, Stephen;Dyer, Fiona M. V.;Fenesha, Fatma;Patel, Anjli;Campbell, Ciara;Crowley, Niamh;Millett, Declan T.
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Resin-modified glass ionomer cement v composite for orthodontic bonding; a randomised controlled trial

Benson PE PhD FDS (Orth)
University of Sheffield, School of Clinical Dentistry, Sheffield UK

Alexander-Abt J BDS FDSRCS Cert Ortho (NYU)
Inline Orthodontics, Stevenage, Hertfordshire, UK

Cotter S BDS NUI, MFDRCSI, MFGDP(UK), MDentSc, MOrthoRCSEng
Private Orthodontic Practice, Killarney, Co. Kerry, Republic of Ireland

Dyer FMV BChD, FDS, MMedSci, MOrth RCS, FDS (Orth) RCPS
The Orthodontic Centre, Sheffield, UK

Fenesha F BDS, DClinDent (Orthodontics), MOrth RCS Ed
University of Sheffield, School of Clinical Dentistry, Sheffield UK

Patel A BDS MOrth MSc FDS (Orth)
Hightown Orthodontics, Crewe, Cheshire, UK

Campbell C BA BDSc MFDS MSc MOrth DClinDent FDS (Orth)
Cork University Dental School & Hospital, Wilton, Cork, Republic of Ireland.

Crowley N BDS NUI, FDS RCSI, MOrth RCS (Eng), MDent.Sci (Leeds)
Cork University Dental School & Hospital, Wilton, Cork, Republic of Ireland.

Millett DT BDSc DDS FDS DOrth MOrth FHEA
Cork University Dental School & Hospital, Wilton, Cork, Republic of Ireland.

Contributions
Philip Benson and Declan Millett wrote the protocol, obtained ethics and other research approvals, recruited participants, collected, analysed and interpreted data and produced the initial report. Fatma Fenesha collated, analysed and interpreted the data and produced the initial report. Jonathan Alexander-Abt, Stephen Cotter, Fiona Dyer, Anjli Patel, C Campbell and N Crowley recruited participants, collected data, viewed and amended the initial report. All the authors have seen the final report.

Corresponding Author
Philip Benson
Academic Unit of Oral Health, Dentistry and Society,
School of Clinical Dentistry,
Claremont Crescent,
Sheffield UK
S10 2TA
p.benson@sheffield.ac.uk
Tel: +44 114 215 9319
Fax: +44 114 215 9414

Abstract

Introduction: Aimed to compare the incidence of new demineralised lesions (DLs) and bond failures between two groups of participants wearing fixed orthodontic appliances bonded with either light-cured resin modified glass ionomer cement (RM-GIC) or light-cured composite (LCC).
Methods: Multi-centre (six centres: 2 teaching hospitals, 4 specialist orthodontic practices), single-blinded, superiority RCT with two parallel groups. Patients aged 11 years or older, in the permanent dentition and about to start fixed orthodontic treatment were randomly allocated to either have RM-GIC or LCC for bonding brackets, forward of the first molars. Pre-treatment and day-of-debond digital photographic images were taken of the teeth and assessed by up to 5 clinical and 3 lay assessors for the presence or absence of new DLs and aesthetic impact. The assessors were masked as to group allocation.
Results: 210 participants were randomised and 197 completed the trial. There were 173 with complete before and after digital images of the teeth. The incidence of new DLs was 24%; but when aesthetic impact was taken into account this was considerably lower (9%). There was no statistically significant difference between the bracket adhesives in the numbers with at least one new DLs (RR 1.25; 95% CI: 0.74 – 2.13; p-value = 0.403) or first time bracket failure (RR 0.88; 95% CI 0.67 – 1.16; p = 0.35). There were no adverse effects.
Conclusions: There is no evidence that use of RM-GIC over LCC for bonding brackets reduced the incidence of new DLs or bond failures. There might be other reasons for using RM-GIC.

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Resin-modified glass ionomer cement v composite for orthodontic bonding; a multi-centre, single-blind, randomised controlled trial

Introduction

Enamel demineralised lesions (DLs) are a common adverse effect of fixed orthodontic appliance treatment. In addition to good oral hygiene and limiting the consumption of fermentable carbohydrate, fluoride has been shown to reduce the prevalence of demineralisation, mainly through the promotion of remineralisation.[1] Unfortunately, there continues to be limited evidence about the most effective means of delivering fluoride in the orthodontic patient to prevent new DLs.[2] Regular professional applications of fluoride varnish at each appliance adjustment visit has been shown to work,[3], as well as regular patient use of high concentration fluoride toothpaste;[4] however, achieving a sustained, low concentration of fluoride in the mouth, without the reliance on patient adherence, would be ideal.

The development of fluoride-releasing glass ionomer cement (GIC) for dental restorations was first reported in 1972.[5] Conventional GIC was found to be too weak for orthodontic bonding,[6] but the use of a stronger, resin-reinforced or modified glass ionomer cement (RM-GIC) was reported in 1995.[7] RM-GIC has not been widely adopted in clinical orthodontic practice, despite some promising laboratory data on the release, recharge and further release of fluoride,[8]; however, clinical evidence for the effectiveness in the prevention of DLs is weak.[9]

The aim of this study was to compare the use of light-cured RM-GIC with a light-cured composite (LCC) resin when bonding orthodontic brackets.

Specific objectives

The study objectives were to answer two main research questions:

- Does the use of RM-GIC for bonding orthodontic brackets reduce the incidence and severity of DLs during fixed orthodontic appliance treatment?
- Is there a higher failure rate of orthodontic brackets when using RM-GIC compared with composite resin?

A number of weaknesses of trial designs in this area of research have been identified in the orthodontic literature to-date.[2] This clinical trial addresses these inadequacies in the following way:

- Used a randomised design, with outcomes that are relevant to clinicians and patients, as well as;
- Parallel groups to reduce the possibility of cross-over of fluoride between different parts of the mouth.
- This was a real world study, undertaken in different clinical settings, to increase the generalisability of the findings, and
- The patients were followed-up to the end of their orthodontic treatment.

Methods

Trial design and any changes after trial commencement This was a multi-centre, randomised controlled trial, with two parallel groups, examining the superiority of light-cured RM-GIC for bonding orthodontic brackets compared with light-cured composite (LCC). Ethical approval was obtained from the National Research Ethics Service Committee Yorkshire and the Humber (Leeds West) Ethics Research Committee (Ref: 07/H1307/153 - 24 October 2007) and Clinical Research Ethics Committee of the Cork Teaching Hospitals (Ref: ECM5(2)5208 - 6 February 2008). After substantial delays research governance approvals were obtained for each site under their own local arrangements. The trial was registered in a clinical trials registration database (ClinicalTrials.gov; NCT01925924). There were no changes to the protocol following trial commencement.

Participants, eligibility criteria, and setting

Participants about to start orthodontic treatment with fixed orthodontic appliances were recruited. The inclusion criteria were:

- 11 years and older;
- Full permanent dentition, requiring upper and lower fixed appliances;
- In good general health;
- Oral hygiene was considered by the operator to be sufficient for fixed appliance treatment.

The exclusion criteria were patients:

- With cleft lip and palate
- Who required combined orthodontic orthognathic surgery.

Eight centres were initially involved in the study (6 specialist orthodontic practices and 2 teaching hospitals); however, one centre only recruited two participants and one recruited seven, data collection from these two

centres was very incomplete and they were withdrawn from the study. Six qualified orthodontists treated the patients through the whole course of treatment, in order to minimise performance bias.

Written consent was obtained from all participants and their parents/guardians, but participants were free to withdraw consent at any stage.

Interventions

Brackets were bonded with either light-cured resin-modified glass ionomer cement (RM-GIC - GC Fuji ORTHO™ LC, GC Corp, Tokyo, Japan) or light-cured composite resin (LCC - Transbond™ XT Light Cure Adhesive, 3M Unitek, Diegem, Belgium). It was left to individual operators to decide whether they would clean the teeth with prophylaxis paste prior to bonding. The teeth of participants in both groups were etched with 37% phosphoric acid for 10 seconds. A thin layer of unfilled resin was applied before placing the brackets bonded with composite. As this was a real world trial, different fixed appliance systems were used between the centres; however, the randomisation process was stratified, so that each operator was allocated an equal number of participants in the RM-GIC and LCC groups. This stratification would help account for confounding factors, such as bracket make, size and method of ligation that might influence the outcome. Molar teeth were banded with glass ionomer cement. To prevent performance bias, each operator was required to have used each bonding adhesive on at least five patients before starting recruitment to the trial.

The patients were reviewed every 4-6 weeks and were instructed to brush their teeth 2-3 times a day with a fluoridated toothpaste. No standard protocol was carried out for the use of fluoride mouthrinses, as problems with compliance have been reported in the literature; therefore, each clinician was asked to carry out their normal instructions in regards to mouthrinses. Operators also used their standard debonding procedure when removing the appliances.

Outcomes (primary and secondary) and any changes after trial commencement. The primary outcome was the presence or absence of new demineralised lesions (DLs), on any teeth from the right second premolar to the left second premolar in both arches, assessed using the pre-treatment and day of debond clinical photographic images. The secondary outcomes were a judgement about the aesthetic appearance of new DLs, as well as the number of first time bond failures (any bracket anterior to the first molars) during treatment, taken from the clinical record.

Assessment of the photographs: Intraoral photographs were taken by the operator treating the patients, using a digital camera, in normal room lighting conditions. All operators had received teaching and experience at taking clinical images, during their specialist studies and continued to routinely take clinical photographs; therefore no extra training was provided for the study. Three views were used in the assessment; right buccal segment, left buccal segment, and frontal. The clinical photographic images were arranged in a PowerPoint presentation. The three start images and the three day of debond images from the same patient were arranged side-by-side (Figure 1) with the question 'Can you see any new white lesions that you think might be due to demineralisation during the brace treatment?' The arrangement of the images and background colour of the presentation, as well as the data collection sheet were piloted by three expert specialist orthodontists initially, using 20 images. When the formatting was agreed the three expert assessors undertook the remaining evaluations independently. If the three initial expert assessors unanimously agreed on the presence or absence of new DLs, then this assessment was considered final and these images were excluded from further assessment. Those images with at least one disagreement were shown to a fourth expert specialist orthodontist assessor and if necessary a fifth expert assessor. A consensus was deemed to have been achieved, when at least three of the expert assessors agreed on the presence or absence of new DLs. All the data were combined and transferred to an Excel® (Microsoft Corp, Redmond, USA) spreadsheet. The images where there was a consensus on the presence of new DLs by at least 3 expert assessors were then shown to 6 assessors; 3 specialist orthodontists and 3 lay people, who were asked if the DLs were of aesthetic concern. A consensus was achieved using a simple majority of judgements.

There were no changes to the outcomes following trial commencement.

Sample size calculation

The sample size was calculated according to Altman for comparing the proportions of binary data.[10] It was determined that a sample size of 200 patients (100 in each group) would be required to detect a 20% reduction in the prevalence of new demineralised lesions between those bonded with RM-GIC compared with those bonded with LCC (significance level of 0.05 and a power of 0.85). To account for an estimated potential withdrawal/dropout rate of 20%, a total of 240 participants would need to be recruited.

Interim analyses and stopping guidelines

No interim analyses were planned. No adverse events were encountered so the stopping guidelines (excessive bond failures) were no introduced.

Randomization (random number generation, allocation concealment, implementation). Randomisation was carried out using computer generated random number sequence to produce a random sample stratified on the operator. This ensured that each operator was allocated the same number of participants in the two groups. Blocked randomisation was used to keep the two groups equal. Subjects were allocated using sequentially numbered opaque envelopes at each centre.

Blinding

The trial was single–blinded, as it was not possible to mask either the clinician carrying out the treatment or the participants to the type of bonding adhesive used; however, the examiners assessing the clinical photographic images were masked to group allocation.

Statistical analysis (primary and secondary outcomes, subgroup analyses) The demineralisation data were binary (Yes, the participant had at least one new DL/No, the participant had no new DL) and independent of each other; therefore, the relative risk ratio (RR) was used to test whether there was a difference in the incidence of demineralization between the two groups. A 2x2 table was constructed according to Altman.[10] According to the null hypothesis, the expected RR value was equal to 1. The 95% confidence interval was constructed to assess the accuracy of the results and the significance level alpha was set at 0.05. Descriptive analyses for the commonly affected teeth and aesthetic judgements of the new DLs are presented.

The bracket failure rate was analysed descriptively as the percentage of the first time bracket failures from the upper and lower right second premolars to the upper and lower left second premolars. The binary data (Yes, the participant had at least one first time bracket failure/No, the participant had no first time bracket failures) were used to calculate the relative risk ratio, 95% confidence interval and p-value for the bond failure between the two adhesives using the same method as the demineralisation data. All participants were analysed in the group to which they were originally allocated.

Results

Participant flow

Recruitment began in February 2009 and was complete by March 2012. The first patient was debonded in September 2010 and the last in December 2014. A total of 210 patients were randomised and the flow of participants through the trial is shown in Figure 2.

Baseline data

The baseline demographic and treatment data are shown in Table 1.

Numbers analyzed for each outcome, estimation and precision, subgroup analyses

Incidence of demineralization: Although 197 participants were followed to the end of their orthodontic treatment 23 had missing day of debond clinical photographic images and one set of clinical photographic images could not be analysed due to poor quality; therefore, there was a complete set of baseline and day of debond images for 173 participants that were independently assessed by up to 5 expert assessors. The agreed evaluations of the assessors after each round of evaluations is shown in Table 2.

A total of 131 participants (RM-GIC 62; LCC 69) patients were judged to have no evidence of new DLs, by at least 3 judges. The total number of participants, who were judged, by at least 3 judges independently, to have developed new DLs following treatment was 42 (RM-GIC 23, LCC 19), which was an overall incidence of 24% in all participants whose images were assessed. The relative risk ratio for new DLs, between the two groups, was 1.25 (95% CI: 0.74 – 2.13), which was not statistically significant (p = 0.403). The number of teeth affected with new DLs was 113. The distribution of the teeth affected is shown in Table 3.

Aesthetic assessment of the lesions: The images of 15 of the 42 participants with new DLs were judged to be of aesthetic concern by a majority of the expert and lay assessors, therefore the overall incidence of aesthetically displeasing new DLs at the end of orthodontic treatment was 9% (15 out of 173). Agreement between the assessors about the aesthetic impact of the new DLs was good, with over 80% agreement for 27 images and over 60% agreement for the remaining 15. There was no difference in the proportion of the new DLs on the teeth bonded with RM-GIC (8 out of 23; 35%) that were judged to be of aesthetic concern compared to those bonded with ICC (7 out of 19; 37%) (p = 0.572, Fishers exact test).

Bracket failure rate: A total of 3588 brackets were bonded during the study (RM-GIC 1727, LCC 1861)). There were 246 first time bracket failures (second premolar to second premolar), which is an overall incidence of

6.9% (RM-GIC 110, 6.4%; LCC 136, 7.3%). The numbers of participants who had at least one first time bracket failure were RM-GIC 44 out of 96 (46%), LCC 53 out of 101 (52%); The relative risk of at least one first time bond failure was 0.88 (95% CI 0.67 – 1.16; p = 0.35). There were large differences in the incidence of first time bond failures between operators (Table 4).

Harms

There were no adverse events during the trial.

Discussion

Main findings

This multicentre, single-blinded, randomised clinical trial found no differences in either the proportions of patients with new DLs or first time bracket failures, when participants were bonded with either composite or RM-GIC. The study followed the design advocated in a recent Cochrane review.[2]

Incidence of demineralization: There is a wide range of reported incidence and prevalence of DLs occurring during fixed orthodontic treatment. This is because various methods have been used to determine the presence of demineralisation, including clinical examination, assessment from photographs and fluorescent techniques. Fluorescent techniques, such as quantitative light-induced fluorescence or QLF, have been validated against destructive methods of measuring demineralisation (usually transverse microradiography or TMR); however, they are very sensitive to small changes in enamel mineral content and are likely to detect demineralisation before it can be seen. Consequently, we believe that the recently reported high proportions of patients with DLs, following orthodontic treatment (many of which might remineralise before becoming an aesthetic or restorative problem), is an over-estimate of the true extent of the problem. [11]

The use of clinical photographic images has the advantage of allowing a clinically relevant assessment to be undertaken, of before and after images at the same time, by a number of masked assessors, without the problems of ensuring and maintaining calibration of clinical judges, throughout a clinical trial, which in orthodontics is usually lengthy. The use of multiple assessors is important, because we found that there was unanimous agreement between 3 assessors, on the presence or absence of new demineralised lesions, for only 55% of participant images (Table 5). A minimum consensus of agreement between three assessors was achieved for 76% of participant images after 4 assessments, whereby a 5th assessor was involved to achieve a final consensus. No special filters were used to reduce reflection from the flash, which would complicate the photographic equipment required. It was decided that by using images of the same teeth, taken at different angles, the assessor could determine if a DL is present or not.

The overall incidence of participants in our study, with new DLs following orthodontic treatment (24%), as well as the teeth affected, are very similar to that reported in two recent, large scale RCTs, involving fluoride products.[3, 4] These studies also employed before and after clinical photographs to record the presence or absence of new DLs and masked judges to undertake the assessments. Although these studies did not report on the aesthetic impact of the DLs they both used the same index to assess the DLs. They found that a large majority of lesions were classified as 'Slight white spot formation (thin rim)' and, therefore, likely to be of minimal aesthetic consequence. We believe that our finding of a 9% overall incidence of aesthetically displeasing DLs following orthodontic treatment is closer to most clinicians' experiences of this adverse event. To illustrate the difference between images that were considered aesthetically displeasing or not, the images of one patient are presented, who was judged to have new DLs following orthodontic treatment, but which were unanimously considered not to be of aesthetic impact to the outcome of the treatment (Figure 3). These images can be contrasted with those of another participant with new DLs which were unanimously considered to be aesthetically displeasing (Figure 4). It is possible that although the incidence of new DLs was not reduced when using RM-GIC there might be a reduction in the severity of DLs when present; however, there was no evidence for this with the proportion of new DLs considered aesthetically displeasing similar between the two groups.

Bracket failure rate: In addition to assessing demineralisation following orthodontic treatment, this study was designed to address some of the short-comings in the literature, that have been found in studies investigating the effectiveness of different bonding adhesives in regard to failure rates.[12] The finding that there were no differences in the failure rate between the two adhesives is contrary to the implied results of many laboratory studies that indicate glass ionomer cement has a lower bond strength than conventional composite resin. This again calls into question the applicability and validity of findings from laboratory studies. Clinicians were advised to only briefly etch (10 secs) the enamel with 37% phosphoric acid, then thoroughly wash the teeth and leave it wet before bracket placement. This method has been shown to increase the bond strength to enamel. [13] Although there were no significant differences between bonding agents, there were large differences between operators, which suggests that care during the bonding procedure is more important in

reducing bond failures, than choice of bonding agent. It also indicates that bonding agents need to be tested in a number of settings and with a number of operators to assess how they perform in the 'real-world'.

Although the use of RM-GIC was shown not to reduce the incidence of demineralisation in this study there might be other advantages for its use. Glass ionomer cements are hydrophilic materials and bond strength has been shown to be greater when the enamel is left wet; therefore, it is a useful bonding adhesive to use in conditions where strict moisture control is difficult. GIC has also been shown to chemically bond to the enamel surface and not simply rely on micro-mechanical attachment following etching. This might make it a useful bonding adhesive where there is altered enamel structure, such as amelogenesis imperfecta.

The biocompatibility and environmental effects of dental materials is important to consider. Composite resins are considered reasonably safe to use in the oral environment; however, there are several reports regarding the cytotoxicity, allergic reactions and oestrogenic effect, particularly to the monomer component. [14-16] RM-GIC is not as biocompatible as conventional GIC, because it still contains monomers; however, the proportions are much lower than in acrylic resin adhesives (10–20% v 50%, depending upon the brand). [17] There is also the issue of cost. Although it is difficult to directly compare the price of the two products, the GC Fuji ORTHO™ LC capsules are more expensive, than a tube of Transbond™ XT Light Cure Adhesive; however, there is a relatively new application system for RM-GIC, an alternative to the capsules, which will reduce the cost of this adhesive. A final potential advantage of RM-GIC is the distinct clinical impression, of those who routinely use this bonding adhesive, that it is much easier and quicker to remove than composite, making the cleaning of cement from the teeth, following debond, less unpleasant for the patient and a potential saving of chairside time for the clinician. This might be a useful avenue of research in future studies.

Limitations

The main weakness of the study was that 37 out of the 210 (18%) participants recruited did not have day of debond photographs with which to assess the presence or absence of new DLs. This is disappointing, but is one of the consequences of undertaking a study in a busy clinical environment, which might not be used (or have time) to collect research data at times requested. Despite this, we believe the results are reliable and generalizable; however further studies, using similar methods and outcomes, need to be undertaken to confirm the findings.

Generalizability

The main strength of the study is that it was undertaken in six centres, four of which were specialist orthodontic practices, where the majority of patients in the UK are treated. Other strengths include, participants were followed to the end of treatment and clinically relevant outcomes were collected and analysed appropriately (with participant as the unit of analysis, not tooth).

The mainstay for the prevention of DLs during fixed orthodontic treatment will be the patients' home use of fluoride toothpaste (minimum F 1450ppm) twice a day, as well as daily fluoride mouthrinses (minimum F 250ppm). The clinician should consider using a high dose fluoride toothpaste (2,800ppm or 5,000ppm) and or regular applications of fluoride varnish (min F 10,000ppm) at every visit for those at high risk. The effectiveness of slow-release fluoride devices for patients wearing fixed orthodontic appliances should also be investigated in the future.[18]

Conclusions

- There was no difference in the incidence of new demineralised lesions in patients who received fixed orthodontic appliances bonded with either a light-cured RM-GIC or LCC;
- There was no difference in the failure rate between the two bonding adhesives;
- Operator has a greater influence on failure rate than choice of bonding adhesive;
- There are other potential advantages to using RM-GIC, including reduced sensitivity to moisture, reduced clean-up time, as well as lower environmental and cytotoxic impacts.

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Conflicts of Interest

GC Corporation donated a proportion of the Fuji ORTHO™ LC bonding adhesive used in this study. The authors report no other conflicts of interest.

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Table and Figure legends

Tables

Table 1 - Baseline demographics and treatment data for participants included in bond failure analysis.

Table 2 – Agreed judgements after 3, 4 and 5 independent, expert evaluations.

Table 3 – Teeth judged to have new DLs (n=111).

Table 4 – First time failure rates for each operator, as a proportion of brackets bonded and proportion of participants with at least one first time bracket failure.

Table 5 – Proportion of images where a consensus was obtained for the presence or absence of new DLs following 3, 4 and 5 assessments.

Figures

Figure 1 – Example of one slide in the presentation for assessment of new DLs.

Figure 2 – Flow of participants through the trial.

Figure 3 – Baseline and day of debond clinical photographic images of participant who was judged to have new DLs that were unanimously considered to not be unaesthetic.

Figure 4 – Baseline and day of debond clinical photographic images of participant who was judged to have new DLs that were unanimously considered to be unaesthetic.

Tables

Table 1 - Baseline demographics and treatment data for participants included in bond failure analysis.

	Composite N = 101			RM-GIC N = 96			All N = 197		
Male:Female ratio (%)	39:62 (39/61%)			41:55 (43:57%)			80:117 (41:59%)		
	N	**Mean**	**SD**	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**
Age (yrs)	99	15.4	3.3	96	15.5	3.3	195	15.5	3.3
Mean treatment duration (mths)	100	17.9	7.0	93	17.3	7.3	193	17.6	7.1
Mean nos. of routine visits	101	12.4	4.0	96	12.3	4.5	197	12.4	4.2
Mean nos. of extra visits	84	1.1	1.4	80	1.3	1.7	164	1.2	1.6

Table 2 – Agreed judgements after 3, 4 and 5 independent, expert evaluations.

		New DLs	
	N	**No**	**Yes**
3 Assessors	173	31	64
4 Assessors	78	4	34
5 Assessors	40	7	33
N		42	131

Table 3 – Teeth judged to have new DLs (n=113).

Tooth	Number	%
Maxillary central incisor	23	20%
Maxillary lateral incisor	28	24%
Maxillary canine	21	19%
Maxillary first premolar	10	9%
Maxillary second premolar	6	5%
Mandibular central incisor	2	2%
Mandibular lateral incisor	4	4%
Mandibular canine	9	8%
Mandibular first premolar	4	4%
Mandibular second premolar	6	5%

Table 4 – First time bond failure rates for each operator, as a proportion of brackets bonded and proportion of participants with at least one first time bond failure.

Operator	First time bond failures	
	Brackets	Participants
1	4.7%	29%
2	5.3%	54%
3	14.3%	85%
4	1.7%	18%
5	6.7%	49%
6	9.5%	71%

Table 5 – Proportion of images where a consensus was obtained for the presence or absence of new DLs following 3, 4 and 5 assessments.

		Agreement		
	N	**Yes**	**No**	**%**
3 Assessors	173	95	78	55%
4 Assessors	78	38	40	76%
5 Assessors	40	40	0	100%

Figures

Figure 1 – Example of one slide in the presentation for assessment of new DLs.

Figure 2 – Flow of participants through the trial.

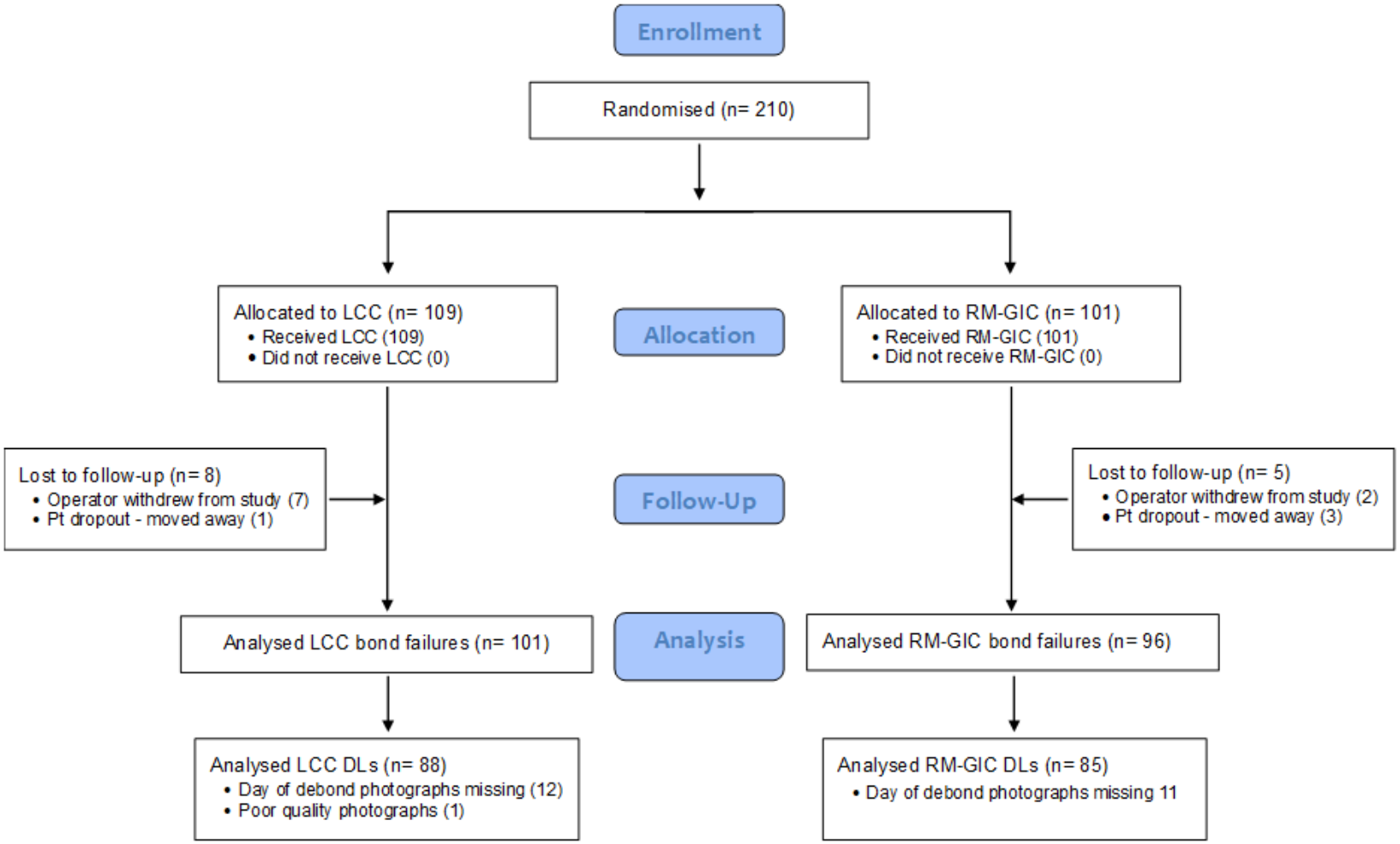

Figure 3 – Baseline and day of debond clinical photographic images of participant who was judged to have new DLs that were unanimously considered to not be unaesthetic.

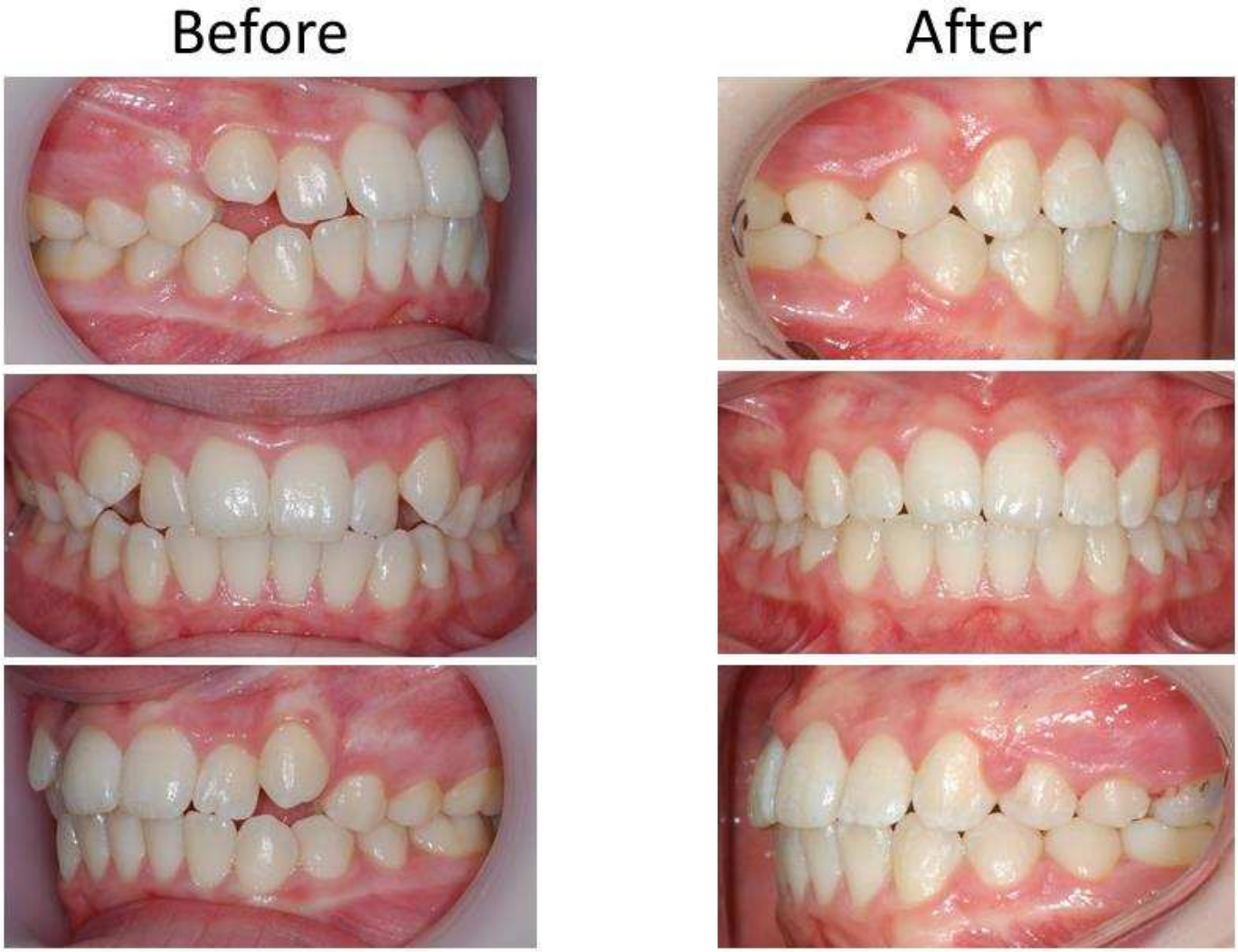

Figure 4 – Baseline and day of debond clinical photographic images of participant who was judged to have new DLs that were unanimously considered to be unaesthetic.